

Applicants: George J. Christ et al.
Serial No: 10/579,705
Filed: October 31, 2008
page 2 of 13

Amendments to Claims:

Please cancel Claims 8, 26 and 34 without prejudice or disclaimer, and amend Claims 1, 9, 21, 25, 35, 43 and 44 as set forth below.

1. (Currently amended) A method of enhancing ~~regulating~~ penile or urinary bladder smooth muscle relaxation ~~tone~~ in a subject, comprising the direct introduction and expression of a DNA sequence comprising a ~~smooth-muscle-specific-promoter~~, smooth muscle alpha actin (SMAA) promoter[[,]] operably linked to a sequence encoding a maxi-K, K_{ATP}, Kv1.5 or SK3 potassium channel protein ~~that regulates penile or urinary bladder smooth muscle tone~~, in a sufficient number of penile or urinary bladder smooth muscle cells of the subject to enhance ~~regulate~~ penile or urinary bladder smooth muscle relaxation ~~tone~~ in the subject.

2-6. (Canceled)

7. (Previously presented) The method of claim 1, wherein the DNA sequence is genomic DNA or cDNA.

8. (Canceled)

9. (Currently amended) The method of claim 1[[8]], wherein the potassium channel protein modulates relaxation of corporal smooth muscle.

10. (Canceled)

Applicants: George J. Christ et al.
Serial No: 10/579,705
Filed: October 31, 2008
page 3 of 13

11. (Original) The method of claim 1, wherein the smooth muscle cells are corporal smooth muscle cells and the potassium channel protein is maxi-K.

12. (Withdrawn) The method of claim 1, wherein the potassium channel protein is Kv1.5.

13-14. (Canceled)

15. (Withdrawn) The method of claim 1, wherein the potassium channel protein is SK3.

16-18. (Canceled)

19. (Previously presented) The method of claim 1, wherein the DNA sequence is introduced by a method selected from the group consisting of instillation therapy, electroporation, DEAE Dextran, cationic liposome fusion, protoplast fusion, creation of an *in vivo* electrical field, DNA-coated microprojectile bombardment, injection with recombinant replication-defective viruses, homologous recombination, nebulization, and naked DNA transfer.

20. (Original) The method of claim 19, wherein the DNA sequence is introduced by naked DNA transfer.

21. (Currently amended) The method of claim 1, wherein the DNA sequence is present in ~~introduced using~~ an EYFP vector.

Applicants: George J. Christ et al.
Serial No: 10/579,705
Filed: October 31, 2008
page 4 of 13

22. (Previously presented) The method of claim 1, wherein the DNA sequence is introduced by means of direct injection into a smooth muscle wall.

23. (Withdrawn) The method of claim 22, wherein the smooth muscle is the bladder.

24. (Canceled)

25. (Currently amended) The method of claim 1, wherein the subject has heightened contractility of a smooth muscle and enhanced relaxation ~~regulation of the tone~~ of the smooth muscle results in less heightened contractility of the smooth muscle in the subject.

26. (Canceled)

27. (Previously presented) The method of claim 1, wherein the subject has a dysfunction selected from the group consisting of erectile dysfunction; urinary incontinence; and bladder dysfunction.

28. (Original) The method of claim 27, wherein the dysfunction is an erectile dysfunction.

29. (Original) The method of claim 11, wherein the subject has an erectile dysfunction.

Applicants: George J. Christ et al.

Serial No: 10/579,705

Filed: October 31, 2008

page 5 of 13

30. (Previously presented) The method of claim 28, wherein the erectile dysfunction results from incomplete relaxation of smooth muscle due to neurogenic dysfunction, arteriogenic dysfunction, and/or veno-occlusive dysfunction.

31. (Withdrawn) The method of claim 27, wherein the dysfunction is a bladder dysfunction.

32. (Withdrawn) The method of claim 31, wherein the bladder dysfunction results from bladder overactivity.

33. (Previously presented) The method of claim 27 wherein the dysfunction is treated.

34. (Canceled)

35. (Currently amended) A method of treating erectile dysfunction in a subject, comprising the direct introduction and expression of a DNA sequence comprising a ~~smooth muscle specific promoter~~, smooth muscle alpha actin (SMAA) promoter[[,]] operably linked to a sequence encoding a potassium channel protein that enhances relaxation of ~~regulates~~ corporal smooth muscle ~~tone~~, in a sufficient number of corporal smooth muscle cells of the subject to enhance relaxation of ~~regulate~~ corporal smooth muscle ~~tone~~ in the subject and thereby treat the subject's erectile dysfunction.

36. (Original) The method of claim 35, wherein the potassium channel protein is maxi-K, K_{ATP}, Kv1.5, or SK3.

Applicants: George J. Christ et al.
Serial No: 10/579,705
Filed: October 31, 2008
page 6 of 13

37. (Canceled)

38. (Withdrawn) The method of claim 36, wherein the potassium channel protein is Kv1.5.

39-41. (Canceled)

42. (Withdrawn) The method of claim 36, wherein the potassium channel protein is SK3.

43. (Currently amended) The method of claim 1, wherein using the smooth muscle alpha actin (SMAA) ~~specific~~ promoter ~~SMAA~~ operably linked to a DNA sequence encoding the potassium channel protein is at least as effective in enhancing relaxation of the regulating smooth muscle ~~tone~~ in a subject as using a viral promoter operably linked to the DNA sequence encoding the potassium channel protein.

44. (Currently amended) The method of claim 35, wherein using the smooth muscle alpha actin (SMAA) ~~specific~~ promoter ~~SMAA~~ operably linked to a DNA sequence encoding the potassium channel protein that enhances relaxation of ~~regulates~~ corporal smooth muscle ~~tone~~ is at least as effective in treating erectile dysfunction in a subject as using a viral promoter operably linked to the DNA sequence encoding the potassium channel protein.